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(54) Title: BONE CEMENT (57) Abstract A bone cement for use in the cementing of prostheses, especially prostheses components for joint caps and bone marrow canals. The bone cement comprises polymethylmethacrylate, filler material in the form of particles of glass fiber or quartz having a particle size of 4 - 8 microns, and a silver ion-releasing material in the form of colloidal silver (silver salt).		

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BONE CEMENT

The invention relates to bone cement especially for cementing prostheses, in particular prostheses components for joint caps and bone marrow canals.

In 1965 a hip prosthesis was developed for use by elderly persons with fractures of the neck of the femur, because the conventional pins which had been used since 1938 had given such poor results. In 1970 this hip prosthesis was developed further into a so-called total prostheses for use on patients with arthrosis, or arthritis of the hip joint owing to wear. With this type of prostheses, one could reconstruct joints in which the cartilage had become worn down both in the cap of the joint and on the head of the joint. This prostheses, named after its inventor, Tor Christiansen, has been patented.

A number of similar prostheses have gradually come on the market. To improve the stability of the prostheses component in the cap of the joint and the bone marrow canal, surgeons began to cement them in place with polymethylmethacrylate, a cement which dentists used earlier as a filling material for tooth cavities. Subsequent examinations of patients with hip prostheses cemented with this cement, however, have shown that the cement has not been strong enough and that it also may be broken down in the organism by the enzyme catalase. Furthermore, injuries to the surrounding bone have also been recorded, owing to the high curing temperature of the cement and to the cytotoxic liquid, the monomer, which is necessary for the curing process. The injuries to the bone tissue are probably the cause of the not-infrequent infections which often occur in the bone tissue many months later.

The object of the invention is to provide an improved cement which reduces or preferably eliminates the above detrimental effects.

Thus, the invention relates to a bone cement which is characterized by comprising polymethylmethacrylate, a filler material and a silver ion-releasing material.

The new cement is substantially stronger than the cement used previously, as may be seen from the table found below. The increased strength is obtained by the addition of filler in the form of particles of glass fiber or quartz having a particle size of 4 - 8 microns. To reduce or eliminate the fateful complication which a post-operative infection is; a silver ion-releasing material is also added to the cement, preferably in the form of colloidal silver having an express germicidal and anti-bacterial effect.

Colloidal silver solutions are combinations of insoluble forms of silver such as iodides, chlorides, oxides, etc., with protective colloids, usually organic. The insoluble forms of silver are precipitated in the presence of the protective colloids (for example, gelatins) in such manner that the particle size is very small and the particles do not settle but remain in suspension, and the resulting liquid has many of the advantages of an actual solution. These small particles of silver compounds act as reservoirs which release silver ions in a controlled manner and in small amounts; the actual concentration of silver ions will vary according to the nature of the silver compound present. As opposed to silver nitrate, for example, which has been used in medical applications, this colloidal silver has a so-called oligodynamic effect,



in that silver ions are continuously released over a long period of time. The silver ions will pass through the membrane of the bacteria and into the DNA molecule, in this way preventing propagation of the bacteria. The ratio of the three components of the bone cement mixture can vary as may be seen from the table found below, which shows the results of tests carried out by Det Norske Veritas.

When pure polymethylmethacrylate cement is cured at room temperature, the curing time is about 6 - 7 minutes and the curing temperature rises to about 90°C for a 10-mm thick layer. In the case of cement to which 25% glass fiber or quartz has been added, the curing time is 12-14 minutes under similar conditions. For cement with 50% quartz added, the curing time is 20-25 minutes and the curing temperature about 45°C. Since a curing time of as long as 20-25 minutes is impractical, the preferred bone cement comprises 65% polymethylmethacrylate with an addition of 30% quartz particles and 5% colloidal silver.

Quartz is preferred to glass fiber particles because the quartz particles are more irregular and thus provide a larger surface area than glass fiber particles. As mentioned above, the particle size for either quartz or glass fiber is between 4 and 8 microns. The larger surface area of the quartz particles may possibly help to make the cement less toxic by absorbing monomers, and one thereby also avoids the harmful high curing temperature.

Bending tests were carried out at Det Norske Veritas on test rods made of polymethylmethacrylate alone and on test rods made of the bone cement of the invention. The results were as follows:

BENDING TEST

Standard utilized	ISO/R 178			
Test Rod dimensions	4 x 10 x 80 mm			
Bending rate	2 mm/min			
Storage	16 x t			
Test Sample	Dimensions mm	Bending ^x module N/mm ²	Bending strength N/mm ²	Bend to break mm
A 1	3.9 x 10.0	2408	58.0	4.3
A 2	4.0 x 10.0	2688	66.0	4.2
B 1	4.0 x 10.0	5120	50.5	2.3
B 2	4.0 x 10.0	4941	47.7	2.2
D 1	4.0 x 10.0	4966	34.5	1.7
D 2	3.9 x 10.0	4815	35.0	1.7
E 1	4.0 x 10.0	6144	28.2	1.1
E 2	4.0 x 9.9	6723	27.8	1.0

^xBending module measured as secant module with a deformation equal to 10% of the thickness of the test sample.

- A = pure cement (polymethylmethacrylate).
- B = 70% by volume polymethylmethacrylate, 25% by volume glass fiber, 5% colloidal silver
- D = 70% by volume polymethylmethacrylate, 25% by volume quartz, 5% colloidal silver
- E = 50% by volume polymethylmethacrylate, 45% by volume quartz, 5% colloidal silver

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In these tests, the bone cement "Simplex" was used for comparison purposes; the three types of bone cement used today in hip surgery all consist of polymethylmethacrylate.

The bone cement of the invention should preferably be used for the cementing of prostheses, especially prostheses components in joint caps and bone marrow canals, and the results obtained up to now have been very satisfactory.



P a t e n t C l a i m s :

1. A bone cement containing polymethylmethacrylate as a main component, characterized in that it also contains filler material in the form of particles of glass fiber or quartz having a particle size of 4 - 8 microns and a silver ion-releasing material in the form of colloidal silver (silver salt).
2. A bone cement according to claim 1, characterized by comprising
 - 70 - 50% by volume polymethylmethacrylate
 - 25 - 45% by volume quartz or glass fiber particles
 - 5% by volume colloidal silver (silver salt).
3. A bone cement according to claim 2, characterized by comprising
 - 65% by volume polymethylmethacrylate
 - 30% by volume quartz particles
 - 5% by volume colloidal silver (silver salt).
4. Utilization of the bone cement according to claims 1 - 3 for the cementing of prostheses, especially prostheses components in joint caps and bone marrow canals.



INTERNATIONAL SEARCH REPORT

International Application No. PCT/NO81/00044

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ¹ According to International Patent Classification (IPC) or to both National Classification and IPC ³ A 61 F 1/00, A 61 K 31/78								
II. FIELDS SEARCHED <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Minimum Documentation Searched ⁴</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 20%; border-bottom: 1px solid black;">Classification System</th> <th style="border-bottom: 1px solid black;">Classification Symbols</th> </tr> <tr> <td style="padding: 5px;">IPC 2</td> <td style="padding: 5px;">A 61 K 5/00</td> </tr> <tr> <td style="padding: 5px;">IPC 3</td> <td style="padding: 5px;">A 61 F 1/00, 1/03, A 61 K 6/00, 31/74, 31/765, 31/78.../...</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵</div> <p style="margin-top: 10px;">SE, NO, DK, FI classes as above</p>			Classification System	Classification Symbols	IPC 2	A 61 K 5/00	IPC 3	A 61 F 1/00, 1/03, A 61 K 6/00, 31/74, 31/765, 31/78.../...
Classification System	Classification Symbols							
IPC 2	A 61 K 5/00							
IPC 3	A 61 F 1/00, 1/03, A 61 K 6/00, 31/74, 31/765, 31/78.../...							
III. DOCUMENTS CONSIDERED TO BE RELEVANT ^{1,6}								
Category ⁷	Citation of Document, ^{1,6} with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹⁸						
Y	DE, A1, 2 906 413 (S.E.P.C.-S.A.R.L., SOCIÉTÉ D'EXPLOITATION DES PROCÉDÉS COATEX) 10 January 1980, pages 11-12							
Y	US, A, 3 932 627 (HARRY W MARGRAF) 13 January 1976							
A	DE, B2, 2 724 814 (KULZER & Co GmbH) 7 December 1978							
A	US, A, 2 347 567 (EDWARD J KRESSE) 25 April 1944							
A,P	WO, A1, 81/02567 (NATIONAL RESEARCH DEVELOPMENT CORPORATION) 1 October 1981							
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IV. CERTIFICATION								
Date of the Actual Completion of the International Search ⁸ 1982-02-19	Date of Mailing of this International Search Report ⁹ 1982-02-26							
International Searching Authority ¹ Swedish Patent Office	Signature of Authorized Officer ¹⁵ <i>Stefan E. Lindén</i> Stefan E. Lindén							

BAD ORIGINAL

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

II

Fields Searched (cont)

IPC 3 C 08 L 33/10, 33/12

US Cl 3:1, 1.91; 424:78, 81

VI ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE 10

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers because they relate to subject matter is not required to be searched by this Authority, namely:

2. ☐ Claim numbers because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out 11, specifically:

VII ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING 11

This international Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims: it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the international Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

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